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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

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MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,821	WELCHER ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10,51-55,70 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10,51-55,70 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/2003 has been entered.

2. Receipt of applicant's arguments and amendments filed on 9/26/03 are acknowledged.

Claims 1, 4, 6-8, 10, 51-55, 70, 72 and amended claim 5 are pending and under consideration by the Examiner

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 9/26/03:

(i) the objections to claims 1-8, 10-11, 51-55, 70-71;

(ii) the rejection of claims 1-8, 10-11, 51-55, 70-71 under 35 U.S.C. 112, first paragraph for written description;

(iii) the rejection of claims 1-8, 10-11, 51-55, 70-71 under 35 U.S.C. 112, second paragraph;

(iv) the rejection of claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Hillier et al. (1997); and

(v) the rejection of claims 4-8, 10-11, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (1997).

4. Applicant's arguments filed on 9/26/03, have been fully considered but were deemed persuasive in part. The issues remaining are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 101/112

6. Claims 1, 4-8, 10, 51-55, 70, 72 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02).

Claims 1, 4-8, 10, 51-55, 70, 72 are drawn to an invention with no apparent or disclosed patentable utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

The instant invention is directed to an isolated nucleic acid molecule comprising SEQ ID NO:1 encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2. The specification on page 107, lines 29-34, discloses that Agp-69406-a1 cDNA was identified based on homology to a mouse gene (agp-65220-a1), and homology based searches identified a 428 nucleotide fragment which upon translation displayed homology to the human IgER/FC RI. However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the protein encoded by the claimed nucleic acid molecule. Instant specification only discloses that the protein encoded by the claimed nucleic acid shares homology to human IgER/FC RI (page 107, last 3 lines). The instant specification

asserts that the claimed nucleic acid encodes a CD20/IgE-receptor like polypeptide but there is no demonstration or even a disclosure in the instant specification about the activities of the polypeptide encoded by the claimed nucleic acid.

Therefore, there is little doubt that, after further characterization, if the instant polynucleotide and the protein it encodes are found to be members of the human IgER/FC RI, they would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Applicants argue that the polynucleotides of the instant invention can be used in the detection of testicular cells because the gene corresponding to SEQ ID NO:1 has been shown to be expressed predominantly in this cell type. However, contrary to Applicants arguments, the employment of a polynucleotide of the instant invention as a tissue specific marker for testicular cells is not a substantial or specific utility since testicular cell specific polynucleotides and proteins were already known in the art. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the

presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

Applicants argue that the instant polynucleotide is expressed in testicular cells and because the instant polynucleotide was also detected in other tissues and cancer cells, does not prevent use of polynucleotides of the invention to detect testicular. Applicant has traversed this rejection on the premise that the disclosure that the polynucleotide of the instant invention is predominantly expressed in a single cell or tissue type indicates that the tissue sample contains that tissue. However, contrary to Applicants arguments, the issue here is that a nucleic acid can be patented even if it encodes no protein, provided the nucleic acid has a substantial disclosed utility. When such a nucleic acid can be used as a marker for a disease or disorder or as a promoter to obtain the production of a recombinant protein in a host cell, that nucleic acid has substantial and specific utility. A protein of unknown function would also have utility if it can be employed as an indicator of a diseased state of the presence of a disorder. The only disclosed function for a nucleic acid of the instant invention is that it is expressed in testicular cells. However, Applicants have failed to show, for example, differential expression of the instant nucleic acid in normal testicular tissue and in disease tissue.

Applicants argue that the instant polynucleotide of SEQ ID NO:1 is specifically located in a particular region on a particular human chromosome and therefore can be used as a chromosomal marker for chromosome 11 (11q12-13). Applicants also argue that there is only one gene at the exact locus on chromosome 11 corresponding to SEQ ID NO:1. However, contrary to Applicants arguments, the employment of the nucleic acid, as a probe or as a

chromosomal marker is not a substantial or specific utility, because the instant polynucleotides are not diagnostic of a disease and there is no evidence on the record that they are associated with any diseases such as non-Hodgkin's lymphoma or any allergic reaction which are associated with rearrangements in chromosome 11 (q12-13). As argued by the Examiner previously, such utilities are analogous to the assertion that a particular DNA can be employed as a molecular weight marker, which is neither a specific or substantial utility. Applicant is not being required to identify a physiological process mediated by the protein encoded by the claimed nucleic acid and a disease or disorder for which that protein or nucleic acid is a marker. Applicant is only required to identify one substantial credible utility and, as stated in the previous office action, the employment of this nucleic acid only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form".

The examiner must simply provide sound reasoning in support of a conclusion that an element is lacking from a specification, and this has been done. In the instant case, it is the responsibility of Applicant to disclose a specific utility for the claimed invention and factually unsupported assertions like those presented i.e. in detection of testicular cells, is not a specific utility on its face that it need not be "proven" wrong.

The following is an excerpt from M.P.E.P. 2138.05:

Utility for the invention must be known at the time of the reduction to practice. Wiesner v. Weigert , 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); Azar v. Burns , 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be

actually reduced to practice unless the composition and the product produced by the method have a practical utility); Ciric v. Flanigen , 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); Engelhardt v. Judd , 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); Rey - Bellet v. Engelhardt,181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." Bindra v. Kelly , 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first inter mediate. However, a strong probability of utility is not sufficient to establish practical utility.); Wu v. Jucker , 167 USPQ

467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see Nelson v. Bowler , 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.)."

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:
"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Claims 1, 4-8, 10, 51-55, 70, 72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose any biological activity for the protein encoded by the claimed nucleic acid, therefore, there is no

specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The fact that the claimed nucleic acid encodes a protein that has homology to human IgER/FC RI is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
October 10, 2003